UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION, THIS DOCUMENT RELATES TO: *Track Three Cases*	MDL. 2804 Case No. 1:17-md-2804 Judge Dan Aaron Polster

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE ANNA LEMBKE

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The Court should deny Defendants' motion to exclude "all or part" of Dr. Anna Lembke's opinions. Defs.' Br. Supp. 1, ECF No. 3802 (notice of service). Defendants do not point to any one of Dr. Lembke's fifteen separate opinions they believe should be withheld from the jury. Instead, Defendants make vague complaints that leave the Court with the impossible task of mapping those complaints onto Dr. Lembke's specific testimony. Apart from their incurable vagueness, Defendants' complaints are unsupported by the law or the facts. Defendants ignore Dr. Lembke's relevant qualifications, manufacture nonexistent opinions they insist Dr. Lembke cannot offer, and assert legal conclusions based on lawyers' say-so unsupported by legal authority. Defendants' request that the Court adhere to its exclusion of Dr. Lembke's "marketing causation" opinions in Track One likewise fails to (1) identify a single opinion Defendants believe would be subject to the Court's prior order; and (2) acknowledge that the Court is now presented with a more robust foundation of Dr. Lembke's qualifications, on which two courts have held Dr. Lembke qualified to offer the same testimony that she proffers here. In short, more is required to short-circuit the adversary process. Defendants' motion fails.

BACKGROUND

Dr. Lembke is among the most highly credentialed experts in the United States as a psychiatrist specializing in addiction medicine and its intersection with pain management. In her position at the Stanford University School of Medicine, Dr. Lembke "occup[ies] the classic three-legged stool of academic medicine": she is at once a clinician, a researcher, and a teacher. Lembke Dep. 9:5–6 (May 28, 2021), ECF No. 3859-15. For the past two decades, Dr. Lembke has researched and lectured on "a diversity of topics related to psychiatry, addiction, and pain." Report 1 (Apr. 16, 2021), ECF No. 3852-8; *see also id.* at 7 ("My research began circa 2001"). For the past fifteen years, "a significant proportion" of Dr. Lembke's patients have been users of prescription opioids. *Id.* at 1. For the past decade, Dr. Lembke has devoted much of her

professional attention to the specific problem of opioid overprescribing. *See* Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* 2–3 (2016) ("The extent of the problem was brought home to me in 2011.").

In her clinical practice, "[a]pproximately 50 percent" of Dr. Lembke's patients have an opioid use disorder. Lembke Dep. 10:17 (May 28, 2021), ECF No. 3859-15. As a researcher and teacher, Dr. Lembke has written and lectured extensively on the subject of this nation's opioid crisis, its causes, and its effects on the public health. *See* Report 2–7 (Apr. 16, 2021) (summarizing this work), ECF No. 3852-8. In these capacities, Dr. Lembke has "interacted with pharmacies and pharmacists thousands of times" as one-half of the "partnership between professionals" necessary to protect patient safety, especially in the context of controlled substances. *Id.* at 6. Dr. Lembke is likewise thoroughly familiar with the obligations imposed on both halves of the partnership by the Controlled Substances Act. *Id.* Further particulars of Dr. Lembke's background and qualifications are set forth below as they become relevant.

STANDARD OF DECISION

The standard for admissibility of expert testimony under Federal Rule of Evidence 702 is fully set forth in *Plaintiffs' Opposition to Certain Defendants' Daubert Motion to Exclude the Opinions Offered by James Rafalski*, to which the Court is respectfully referred.

ARGUMENT

I. Defendants' Failure to Identify the Testimony They Seek to Exclude Is Reason Alone to Deny Their Motion

In the first place, it is Defendants' job—not Plaintiffs' or the Court's—to identify the specific opinions Defendants seek to exclude. *See* Opinion and Order 7 (Sept. 3, 2019) ("Defendants fail to identify the specific opinions or the particular testimony of Kessler they seek to exclude. … The Court will not make non-specific rulings on the record before it."), ECF

No. 2558, *available at* 2019 WL 4165021; *see also RCHFU, LLC v. Marriott Vacations Worldwide Corp.*, No. 16-cv-01301, 2020 WL 2839302, at *3 (D. Colo. June 1, 2020) ("The burden is on the moving party to identify the specific opinions it seeks to exclude." (internal alterations omitted)); *Alcatel USA, Inc. v. Cisco Sys., Inc.*, No. 4:00cv199, 2002 WL 34357200, at *1 (E.D. Tex. May 7, 2002) ("the Court has neither the time nor the inclination to sift through the approximate 50 pages of Dr. Campbell's Expert Report in search of an offending provision"). Defendants' motion does not do so, and for this reason alone Defendants' motion should be denied.

II. Dr. Lembke Is Qualified to Opine on the Pharmacies' Role in the Opioid Epidemic.

Defendants argue Dr. Lembke is not qualified to opine "regarding the practice of pharmacy or dispensing policies." Defs.' Br. Supp. 4 (capitalization regularized), ECF No. 3802 (notice of service). Defendants point to no specific opinion in Dr. Lembke's report they believe she is unqualified to offer. By their vague, ill-defined objection, Defendants would apparently prohibit Dr. Lembke from saying anything about pharmacies at all. Defendants' citations to two inapposite out-of-circuit cases and a handful of deposition quotations taken out of context do not support this extreme position. Instead, Dr. Lembke's expertise is directly relevant to Defendants' failure to prevent diversion of opioids to illegitimate uses.

A. Pharmacy and Medicine Are Closely Related Fields.

Federal law establishes a prescriber's "responsibility for the proper prescribing and dispensing of controlled substances" in the same sentence as it establishes a dispenser's "corresponding responsibility" for the same. 21 C.F.R. § 1306.04(a). These duties are indeed closely linked. For example, federal law tasks both physicians and pharmacists with identifying and investigating many of the identical signs of potential diversion or illegitimate prescribing,

such as co-prescribing of inappropriate drug "cocktails"; "doctor shopping"; early refills; and multiple prescriptions for the same drug or class of drugs. *See* Report 99–100 (Apr. 16, 2021), ECF No. 3852-8. Both physicians and pharmacists have parallel rights to access, and responsibilities to use, prescription drug monitoring programs (PDMPs) such as the Ohio Automated Rx Reporting System (OARRS) as a primary source of that type of information. *See id.* at 99.

Likewise, the practice of medicine and the practice of pharmacy in general are closely related with respect to the prescribing and dispensing of controlled substances. In recognition of this close relationship, courts have allowed pharmacists to testify to a physician's conduct or other matters within the practice of medicine. *See Romero v. Hanisch*, No. Civ. 08-5040, 2010 WL 1812578, at *6 (D.S.D. May 3, 2010) (citing cases); *see especially United States v. Smith*, 573 F.3d 639, 653 (8th Cir. 2009) (permitting Carmen Catizone (who is also a pharmacist witness in CT3) to testify to "standard of care to which a doctor must adhere in order to prescribe properly a controlled substance" and finding that "[d]espite the fact that Catizone was not a medical doctor, … his testimony regarding the type of information a doctor should have to prescribe a particular drug, and whether Dr. Mach met that standard, fell within his expertise.").

Professionals outside litigation recognize the close relationship between medicine and pharmacy as well. Medical doctors professionally opine on pharmacy practices in peer-reviewed literature. *See, e.g.*, Mitch Betses & Troyen Brennan, *Abusive Prescribing of Controlled Substances—A Pharmacy View*, 369 NEW ENG. J. MED. 989 (2013) (M.D. coauthor). Indeed, Dr. Lembke herself has published on these very issues in the context of controlled substances. *See* Anna Lembke *et al.*, *Our Other Prescription Drug Problem*, 378 NEW ENG. J. MED. 693 (2018) (discussing, and demonstrating Dr. Lembke's particular knowledge and expertise concerning, the

heightened risk of opioids when taken with benzodiazepines—one of the primary "red flags" specified in Defendants' documents); Anna Lembke, *Be Sure to Check the PDMP Before Prescribing Controlled Medications*, PSYCHIATRY ONLINE: PSYCHIATRIC NEWS (June 17, 2016) (discussing, and demonstrating Dr. Lembke's experience and expertise with, the same methods referenced repeatedly in Defendants' policies and procedures for pharmacists to investigate "red flags" for illegitimate prescribing), https://psychnews.psychiatryonline.org/doi/full/10.1176/appi.pn.2016.pp6b2.

B. Dr. Lembke's Knowledge and Experience as a Medical Doctor And an Addiction Expert Qualify Her to Opine on Pharmacies' Dispensing Practices.

Dr. Lembke's own experience illustrates the relationship between pharmacies and physicians described above. As Dr. Lembke explains, in her role as a clinician she has "interacted with pharmacies and pharmacists thousands of times." Report 6 (Apr. 16, 2021), ECF No. 3852-8. Dr. Lembke describes the physician–pharmacist relationship as a "partnership between professionals, with the overarching goal being the safety and best interests of [their] patients." *Id.*; *see also id.* at 99 ("My relationship with pharmacists is collaborative, with the mutual goal of protecting the best interests of patients in receiving the proper medication, and the best interests of the community … ."). This partnership assumes special significance where the physician prescribes and the pharmacist dispenses controlled substances. *See id.* at 99 ("the need for diligent investigation of red flags is an ever-present and recurring topic of discussion with the pharmacists who fill prescriptions for my patients, especially when controlled substances are prescribed"). The closely related functions of physicians and pharmacists arise from the obligations imposed on both partners by the Controlled Substances Act and the unique risks posed by the Schedule II and Schedule III substances. *See id.* at 6 ("as a frequent prescriber of scheduled pharmaceuticals"); *see also* CT1 Lembke Dep. 46:20–47:10 (Apr. 24, 2019)

(discussing history prescribing controlled substances), ECF No. 1979-17; *see generally* 21 U.S.C. § 812(b)(2), (3) (defining risks posed by Schedule II and Schedule III substances).

Contrary to Defendants' suggestion that Dr. Lembke's knowledge of and experience with pharmacies is newly manufactured, Dr. Lembke has consistently maintained her familiarity with pharmacies and pharmacy practice. For example, in Track Two (which involved no pharmacy defendants), Dr. Lembke testified that electronic medical records permit her to understand where her patients are getting their prescriptions filled, and that, "[e]specially" where controlled substances are prescribed, she speaks with the dispensing pharmacist in "more than 50 percent" of cases. CT2 Lembke Dep. 46:5–48:14 (Sept. 17, 2020), ECF No. 3859-13. Given that her interactions with pharmacists have occurred "thousands of times," these interactions with pharmacists have been a very common source of Dr. Lembke's experience with pharmacists and their practices. Report 6 (Apr. 16, 2021), ECF No. 3852-8.

Furthermore, Dr. Lembke's unquestioned expertise in addiction, and in opioid addiction specifically, necessarily requires her to engage with pharmacies' dispensing policies and practices. Pharmacies are the "last line of defense" before prescription opioids reach the public, including those for whom they have been prescribed for medical purposes, those who have obtained prescriptions to maintain their addiction, and those to whom the drugs have been diverted. Report 100 (Apr. 16, 2021), ECF No. 3852-8. As Dr. Lembke explains, "[o]ne of the biggest risk factors for addiction is simple access to addictive drugs." *Id.* at 12; *see id.* at 16–18 (discussing causal relationship between availability and addiction); *see also id.* at 231–35 (discussing causal relationship between availability and diversion, or "tsunami effect"). By definition, access to and availability of controlled substances depend proximately on the practices of pharmacists who dispense them, as the final link in the opioid supply chain. As Dr.

Lembke's testimony has consistently demonstrated, the entire opioid supply chain is the subject of her professional inquiry and expertise, including the conduct and misconduct of opioid dispensers. *In re Opioid Litig.*, No. 400000/2017, Lembke Dep. 30:5–22 (Jan. 16, 2020) (discussing understanding of pharmacies' responsibilities to ensure patient safety, including prevention of opioid harm), 34:11–23 (role of distributors in opioid epidemic), 35:15–36:8 (role of entire supply chain in opioid epidemic), ECF No. 3859-11; CT1 Lembke Dep. 268:24–269:19 (Apr. 24, 2019) (discussing understanding of pharmacies' responsibilities to ensure patient safety), ECF No. 1979-17.

Defendants complain vaguely, as noted above, about Dr. Lembke's opinions on "the practice of pharmacy or dispensing policies." Defs.' Br. Supp. 4 (capitalization regularized), ECF No. 3802 (notice of service); *see also, e.g.*, *id.* at 5 (not "a pharmacy expert" or "an expert on pharmacy practices"). But to the extent Dr. Lembke opines on these matters, her testimony flows directly from the expertise outlined above, as her summary of her sixth opinion illustrates:

> Pharmacies leveraged their unique and pivotal position in the opioid supply chain to contribute to the unprecedented and unchecked flow of opioid pain pills into the community. They alone had direct contact with opioid manufacturers and distributors upstream, and patients and prescribers downstream. Their coordinated efforts to "create demand" included advertising specific opioid products at the pharmacy counter [and several other listed measures]. By increasing and assuring the supply of opioids and failing to provide effective controls against diversion, pharmacies contributed to opioid misuse, addiction, dependence, and death.

Report 8 (Apr. 16, 2021), ECF No. 3852-8. Defendants advance no cogent argument, and none is conceivable, that a doctorate in pharmacy is required to deliver this opinion to the jury for its consideration. What *is* required is precisely what Dr. Lembke incontestably possesses: expertise in and professional familiarity with the factors driving access to and availability of opioids, in turn driving opioid addiction, overdose, and death; and frequent interactions with pharmacies on

the issues relevant to their "corresponding responsibility" to prevent diversion of controlled substances.

C. Defendants' Attempts to Disqualify Dr. Lembke Fail.

Defendants point to Dr. Lembke's 2019 testimony that she would not "hold [her]self out as having expertise with respect to pharmacy." CT1 Dep. 271:10–13 (Apr. 24, 2019), ECF No. 1979-17. This argument is overly simplistic and unpersuasive. Dr. Lembke's opinions are not provided from the perspective of a "pharmacy" expert, nor need they be offered from that point of view in order to be relevant and admissible. Instead, as discussed above, Dr. Lembke provides critically important opinions from the perspective of a *physician* on topics that are inextricably intertwined with both the medical and pharmacy professions: "red flags" that both professions must investigate for potential diversion or misuse of controlled substances; the importance of diligence and care that both professions must exercise in the investigation of such warnings; specific expertise regarding the dangers of drug "cocktails," one of the most important and hazardous red flags of all; the importance of PDMPs as the most effective means by which *both* doctors and pharmacies can investigate red flags; and, from the perspective of an addiction medicine specialist, the role of Defendants' conduct in allowing the unprecedented access and exposure to opioids that enabled the occurrence of the epidemic of addiction and mortality.[1]

[1] To the extent relevant, the Court may also consider that Rule 702 requires the court, not the witness, to determine the bounds of the witness's expertise. *Watson v. United States*, 485 F.3d 1100, 1105–06 (10th Cir. 2007) (Gorsuch, J.) (citing *Lolie v. Ohio Brass Co.*, 502 F.2d 741, 746 (7th Cir. 1974)). That determination is not well served by substituting, as Defendants suggest, the witness's self-estimation for the court's judgment. "While overly modest expert witnesses may not be exactly an everyday sort of problem in our legal system, neither can we ignore the prospect of mistakenly excluding a witness who really is expert but simply too demure to trumpet … her qualities under cross-examination[.]" *Id.* at 1106. The Court should look not to Dr. Lembke's estimation of herself, but to the body of her training, knowledge, and experience. The latter demonstrates that Dr. Lembke is well qualified to opine on the "pivotal" role pharmacies' play in making opioids available and accessible. Report 8 (Apr. 16, 2021), ECF No. 3852-8.

Defendants reliance on *In re Toy Asbestos*, No. 19-cv-00325, 2021 WL 1111226 (N.D. Cal. Mar. 23, 2021), is unpersuasive because that case is readily distinguishable. There, the proponent of expert testimony "fail[ed] to explain how [the witness's] knowledge, skill, experience, training, and education as a pulmonologist somehow provide[d] relevant insight into what was historically known or knowable about the hazards associated with asbestos." *Id.* at *3. Here, by contrast, Plaintiffs rely not on the mere fact that Dr. Lembke is an addiction specialist, but on the facts that (a) the subject matter of her opinions is common to both professions, and (b) she has devoted a substantial part of her professional career as an addiction specialist to obtaining and communicating "relevant insight" into the very question under discussion: how the opioid supply chain, including pharmacies, flooded the country with opioids, and what effect that "tsunami" had on the public health. *See* Report 231–35 (Apr. 16, 2021) (discussing "tsunami effect"), ECF No. 3852-8.

Defendants also quote a snippet of *United States v. Paul*, 175 F.3d 906 (11th Cir. 1999), but that case is likewise distinguishable. There, the court affirmed exclusion of testimony on handwriting analysis offered by an evidence professor who had coauthored a law review article on its unreliability ten years before and who had done "no further research or writing on the subject" since. *Id.* at 912. "His skill, experience, training and education as a lawyer did not make him any more qualified to testify as an expert on handwriting analysis than a lay person who read the same articles." *Id.* Here, by contrast, Dr. Lembke's nearly ten-year professional engagement with the subject matter of her testimony means she is specially positioned to assess and opine on the material she has reviewed within and outside this litigation—wholly unlike "a lay person who read the same articles." *Id.* Indeed, a court may deem an expert qualified by her professional ability to "read, understand, interpret and rely upon the published literature." *In re Gadolinium-*

Based Contrast Agents Prods. Liab. Litig., No. 1:08 GD 50000, 2010 WL 1796334, at *18 (N.D. Ohio May 4, 2010) (Polster, J.), *opinion modified on reconsideration*, No. 1:08 GD 50000, 2010 WL 5173568 (N.D. Ohio June 18, 2010), *aff'd sub nom. Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014), *and aff'd in part sub nom. Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014) ("The Court finds that [an expert] does not have to have to [sic] be a toxicologist, chemist, radiologist and/or have personally conducted animal studies to be able [to] read, understand, interpret and rely upon the published literature…"); *see also Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp. 2d 420, 439 (E.D.N.Y. 2011) (finding although expert lacked expertise in the specialized area, he was qualified to opine on a biologically "plausible mechanism that ha[d] been identified based on his professional understanding of the relevant literature").

III. Dr. Lembke's Consideration of Aggregate Data Is Neither Unreliable Nor Ill Fitted to This Case.

Defendants assert without argument or authority that consideration of aggregate, nationwide proof "is the opposite" of reliable methodology. Defs.' Br. Supp. 7, ECF No. 3802 (notice of service). This Court has repeatedly rejected this and similar arguments. *See* Opinion and Order 19 n.16 (Feb. 21, 2020) (denying in part motions to dismiss third-party payor claims and allowing "Plaintiffs to use aggregate evidence to attempt to prove causation in the RICO context") (citing *In re Neurotonin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013)), ECF No. 3177, *reported at* 440 F. Supp. 3d 773; Order 4 (Aug. 26, 2019) (denying CT1 motion to exclude testimony of Prof. David Cutler and finding "[t]he Court does not agree with Defendants that Cutler's reliance on aggregate [national] data undermines his opinions' fit with Plaintiff's theory."), ECF No. 2542, *available at* 2019 WL 4011729; Order 8, 8–10 (Aug. 26, 2019) (denying CT1 motion to exclude testimony of Prof. Jonathan Gruber and rejecting

"Gruber's omission of data on the bellwether counties in his quartile analysis as a reason to exclude his opinions"), ECF No. 2531, *available at* 2019 WL 4011855.

The Court has been right to do so because Defendants' assertion has no merit. As the First Circuit has explained, a district court does not abuse its discretion in admitting national data to prove local conditions where such use is "reasonable," specifically where it is "reasonable to assume" that the national and local backgrounds are "similar." *In re Neurotonin*, 712 F.3d at 44. And if a jury finds that such national evidence proves a local condition, its finding will not be disturbed. *See id.* at 45–46; *id.* at 46 ("Weighing the individual testimony presented by Pfizer against the aggregate evidence presented by Kaiser was a task for the jury and district court.").

In this case, Defendants do not even attempt to argue that Dr. Lembke's opinions on pharmacies' role in the opioid epidemic apply to Lake and Trumbull Counties differently than to the rest of the country. Nor do they identify a single opinion of Dr. Lembke's which they believe impermissibly infers local from national conditions. Such arguments would fail even if Defendants had bothered to make them. Dr. Lembke's Track Three report reviews the national activities of national opioid supply chain actors, including national chain pharmacies like Defendants, and assesses their role in creating and perpetuating the national opioid epidemic. Dr. Lembke also discusses these effects in the local contexts of Lake and Trumbull Counties. *See* Report, App'x III 2–7, 7 (Apr. 16, 2021) (discussing how Lake and Trumbull "have been severely impacted by the opioid epidemic"), ECF No. 3852-8. In this light, and absent a showing of material difference between Lake and Trumbull Counties and the country as a whole, the Court should permit the jury to weigh for itself whether and to what extent Dr. Lembke's analyses speak to the local situation.

IV. Whether Dr. Lembke's "Pharmaceutical Opioid Industry" Label Is Misleading in Context Should Be Determined at Trial.

Defendants worry that Dr. Lembke's "Pharmaceutical Opioid Industry" label will unfairly prejudice their defense and mislead the jury. Defs.' Br. Supp. 8, ECF No. 3802 (notice of service). In the first place, Defendants' insistence that they have nothing to do with the "Pharmaceutical Opioid Industry" is contradicted by their own brief and the very testimony they seek to exclude. For example, Defendants admit they offered opioid manufacturers' coupons to their own customers. *Id.* Defendants also collaborated with manufacturers to create "Super Stores" that assured availability and access to an uninterrupted supply of opioids, and partnered with an Industry-funded front group to prepare and distribute a false and misleading brochure regarding the risks and benefits of prescription opioids. *See* Report 81–84, 97–99 (Apr. 16, 2021), ECF No. 3852-8. Dr. Lembke further explains how the entire opioid supply chain, including pharmacies like Defendants, operated in concert to make opioids as easily and widely available as possible. *See id.* at 68–76 (discussing "collaborat[ion]" of manufacturers, distributors, and pharmacies in "promot[ing] sales of opioid pain pills"). Indeed, the opioid industry's concerted efforts to promote opioids have been a central topic of Dr. Lembke's professional research, writing, and teaching in this area, as described in greater detail above.

Setting aside Defendants' flawed factual premise, by its own terms their argument on this point sounds in Rule 403, not Rule 702. *See* Fed. R. Evid. 403 (permitting exclusion to prevent "unfair prejudice" and "misleading the jury"). Defendants' quibbling with Dr. Lembke's word choice does not address any concern of Rule 702 and does not support excluding any of her opinions. The Court should leave each rule to its proper office. And whether, under Rule 403, Dr. Lembke's word choice presents an intolerable risk of prejudice or confusion is best assessed in light of her actual testimony at trial. All agree that Dr. Lembke will be expected at trial to

connect any testimony that does not apply to the opioid industry generally to the conduct of specific Defendants.

V. Dr. Lembke's Red Flag Opinions Are Reliable And Within Her Expertise.

Defendants' final challenge to Dr. Lembke's testimony is unsupported by any authority and premised on two fundamental errors. First, Defendants misunderstand a dispenser's "corresponding responsibility" under the Controlled Substances Act as implemented by I. In language by now familiar to the Court, that regulation provides in relevant part as follows:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

Id. § 1306.04(a). According to Defendants, "[w]hat matters [under § 1306.04] is the subjective 'purpose' of the prescriber in writing the prescription." Defs.' Br. Supp. 10, ECF No. 3802 (notice of service). It may or may not be true that whether a prescriber has complied with § 1306.04 is partly or entirely a subjective inquiry; Defendants offer no legal authority for this straightforward legal question. *But see, e.g.*, *United States v. Katz*, 445 F.3d 1023, 1031–32 (8th Cir. 2006) (sustaining admission of expert testimony that "a doctor who did not follow the [*objective*] standards of care in diagnosis could not have a legitimate medical purpose to write a prescription" (emphasis added)) ("[First,] Dr. Parran *did not testify regarding the subjective mental state* of Dr. Katz … . Second, Dr. Parran's testimony tying standards of care to the existence of a legitimate medical purpose to write a prescription was admissible." (emphasis added)).

But it is indisputably not true of a dispenser's "corresponding responsibility." It has never been suggested by any party in this litigation that a pharmacist's primary duty under the Controlled Substances Act is to plumb the depths of physicians' hearts. Rather, as the issue has always been framed by this Court, by applicable precedent, and by the litigants, a pharmacist's duty is to investigate and resolve *objective* indicia of diversion—that is, "red flags." *See, e.g.*, Catizone Rep. (Apr. 16, 2021) (discussing only objective indicia of diversion), ECF No. 3852-2. This framing is correct under the law. *See, e.g., Jones Total Health Care Pharm., LLC v. DEA*, 881 F.3d 823, 830 (11th Cir. 2018) (*per curiam*) (sustaining revocation of pharmacy's CSA registration and holding evidence of more than 100 prescriptions filled with unresolved and unresolvable *objective* red flags "support[ed] the agency's determination that Jones Pharmacy unlawfully filled numerous controlled substance prescriptions that were not issued for a legitimate medical purpose"). Accepting the contrary would lead to absurd results: for example, that a pharmacist who dispenses opioids to a known doctor-shopping patient fulfills her corresponding responsibility as long as the doctor-shopper has successfully deceived the prescribing doctor. This is not and could not be right.

Second, Defendants' misstatement of the issues arises from their misrepresentation of Dr. Lembke's report. None of the statements to which Defendants object appear there. Rather, each of them was elicited by Defendants at Dr. Lembke's deposition. *See* Defs.' Br. Supp. 9–10 (citing only deposition testimony), ECF No. 3802 (notice of service). These statements were elicited on the subject of doctors' good faith belief in a legitimate medical purpose for a prescription, not on the related but distinct question of pharmacies' corresponding responsibility "for the proper … dispensing of controlled substances"—the primary question germane to Pharmacy Defendants' liability in this lawsuit. 21 C.F.R. § 1306.04(a). Thus, Defendants appear

to have elicited testimony for the sole purpose of arguing it should be excluded. The Court should reject Defendants' attempt to manufacture unreliability in Dr. Lembke's testimony through the introduction of irrelevancies.

VI. Changed Circumstances Justify Reconsideration of the Court's Prior Exclusion of Dr. Lembke's "Marketing Causation" Opinions.

In Track One, this Court ruled "narrowly" that Dr. Lembke was not qualified by specialized training, knowledge, or experience to opine that the opioid industry's marketing and promotion of opioids "caused an increase in the sales and/or supply of prescription opioids." Opinion and Order 12–13 (Aug. 28, 2019) (emphasis added), ECF No. 2549, *available at* 2019 WL 4054998. Not excluded were Dr. Lembke's opinions, among others, that "Defendants misrepresented the risks and benefits of opioids," "how they did so," and "how doctors, in general, rely on such information in making prescribing decisions." *Id.* Without identifying any specific opinion in Dr. Lembke's Track Three report they believe comes within the Court's prior ruling, Defendants ask the Court to "continue to exclude those opinions" here. Defs.' Br. Supp. 1, ECF No. 3802 (notice of service). As discussed above, *see* Part I *supra*, this failure to identify the testimony at issue provides sufficient basis to deny Defendants' request. But even on the merits, this portion of Defendants' motion should be denied because changed circumstances warrant a different conclusion than the one the Court reached in Track One.

Dr. Lembke's report, as well as her deposition testimony provides substantial new or additional evidence of Dr. Lembke's knowledge and experience that was not before the Court in 2019. Defendants simply ignore this evidence, devoting only a single sentence and no analysis to their contention that this Court should reach the same conclusion here that in reach in Track One. But this additional evidence was sufficient to persuade two courts that Dr. Lembke *is* qualified to opine on the cause-and-effect relationship between false and misleading promotion, increased

opioid prescribing, and increased harms. In light of these changed circumstances, and upon consideration of this new evidence, this Court should revisit its prior ruling and find likewise.

A. Dr. Lembke's Expertise in the Effects of Opioid Promotion Has Been Recognized by Peer Clinicians, Peer Researchers, and Major Universities.

Dr. Lembke's Track Three report contains additional information about her expertise that was not before the Court in 2019, as well as a description of additional experience in the intervening two years since that ruling. As Dr. Lembke explains in her Track Three report, since writing *Drug Dealer, MD*,[2] she has given presentations "to doctors, legislators, and the public" on "the causes of the opioid epidemic." Report 5 (Apr. 16, 2021), ECF No. 3852-8. A "significant portion" of this work involves "describing the false and misleading messages promoted by the Pharmaceutical Opioid Industry as detailed in this Report." *Id.*

In presenting on this topic, it has been Dr. Lembke's experience that "audiences of professionals and lay persons alike continue to be misled by the decades-long campaign of misinformation promoted through the Industry's marketing of opioids." *Id.* Her experience is consistent with the opinion of the Association of Schools and Programs of Public Health that "'extensive academic detailing'"—or, in Dr. Lembke's words, "the process of providing accurate information to medical providers about the risks and benefits of a drug, to balance and re-educate after exposure to one-sided and inaccurate messaging"—is required "'to correct the inaccurate and misleading claims previously made'" about opioids by the opioid industry. *Id.* (quoting *Bringing Science to Bear on Opioids* 21, Ass'n of Schools and Programs of Pub. Health (Nov. 1, 2019), https://aspph-wp-production.s3.us-east-1.amazonaws.com/wp-content/uploads/2019/09/

[2] The Court is familiar with Dr. Lembke's authorship of *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop* (2016). *See* Opinion and Order 10 (Aug. 28, 2019), ECF No. 2549, *available at* 2019 WL 4054998; CT1 Report 2 (Mar. 25, 2019), ECF No. 1999-10.

ASPPH.Opioids.FINAL_.11.01.20191.pdf). Dr. Lembke's professional experience diagnosing and combatting the harm caused by the opioid industry's promotion of opioids supports her qualification to speak to that harm's existence and origins.

As Dr. Lembke's Track Three report explains further, she has "taught extensively" on this same subject at Stanford University, Duke University, and other institutions before undergraduates, business students, law students, public health students, and medical students. *Id.* at 6. Of note, Dr. Lembke was specifically invited to give a lecture at Duke University in the fall of 2020, on the subject of "market-driven epidemics," based on her experience and expertise in this area. *Id.* Dr. Lembke's lectures discuss, among other topics, the "continuing impact" of the opioid industry's promotion of opioids "on several generations of doctors" and their "opioid prescribing practices." *Id.* Dr. Lembke's peer researchers "frequently" ask her to review articles for publication on the subject as well. *Id.* The Court should reject Defendants' position that what is good enough for the medical profession, the research community, and this country's best universities is not good enough to be tested by the adversary system. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993).

B. Other Courts Have Accepted Dr. Lembke's Qualifications, as Set Forth in Her Track Three Report, as Sufficient to Permit Her Testimony that False and Misleading Promotion Resulted in Increased Opioid Prescribing and Resulting Harms.

Recognizing Dr. Lembke's knowledge and experience in researching, writing, and teaching about the effects of the opioid industry's promotion of opioids, two other courts in opioids suits have allowed her to opine on the topic. In California, the trial court permitted Dr. Lembke's opinion after a searching inquiry into its foundation:

> Q. Doctor, going beyond your own personal experience, did you reach opinions in this case as to whether the marketing misrepresentations that you identified, the six

> misrepresentations that we discussed, were—caused an increased prescribing of opioids by physicians?
>
> A. Yes, I did reach an opinion about that.
>
> Q. And what is that opinion?
>
> [The court overrules two defense objections to lack of foundation and hearsay.]
>
> Q. And, Dr. Lembke, what is your opinion?
>
> A. My opinion is that the false and misleading messages on the part of the defendants was a significant factor in opioid overprescribing and the development of the opioid epidemic.

People of the State of California v. Purdue Pharma L.P., et al., No. 2014-00725287, Trial Tr. 2,522:2–2,523:5 (Super. Ct. Orange Cnty. May 18, 2021), ECF No. 3859-14; *see also id.* at 2,514:2–2,521:26 (foundation); Pl.'s Br. Opp. 4–7 (discussing qualifications), Ex. A.

Similarly, in New York, the trial court found Dr. Lembke "qualified to offer" the opinions among others that "Defendants' conduct in promoting increased supply and widespread access to prescription opioids has resulted in an epidemic of opioid addiction and overdose death," and that the opioid industry "contributed to the paradigm shift in opioid prescribing through promotional materials." *In re Opioid Litig.*, No. 400000/2017, Decision 15–16 (N.Y. Sup. Ct. Suffolk Cnty. Nov. 12, 2020) (original emphasis),[3] Ex. B; *see also* Hr'g Tr. 33:18–35:10, 79:21–83:11 (Sept. 9, 2020) (discussing academic detailing work), ECF No. 3859-12;

[3] The New York court drew a distinction this Court has not recognized between "promotion" and "marketing," excluding Dr. Lembke's testimony as to "marketing." *In re Opioid Litig.*, No. 400000/2017, Decision 16 n.8 (N.Y. Sup. Ct. Suffolk Cnty. Nov. 12, 2020) (original emphasis), Ex. B. The court's distinction did not impair the substance of Dr. Lembke's testimony on this topic. At trial, in addition to the testimony quoted in the body above, the court permitted Dr. Lembke to testify, for example, that "using the concept of pseudoaddiction" was "false promotion" that "encouraged higher dosage of opioid prescribing." Trial Tr. 78:23–79:2 (July 12, 2021), ECF No. 3859-16; *see also, e.g.*, *id.* at 96:10–14 ("Certainly opioid manufacturers were able to infiltrate every layer of medicine and medicine regulatory bodies and policymakers in order to promote opioids as a class, which in turn increased sales of their opioid products.").

Pls.' Br. Opp. 65–66 (discussing qualifications), Ex. C. Consistent with this ruling, the New York court permitted Dr. Lembke to testify at trial as follows:

> Q. [W]hat is th[e] relationship [you have seen between the promotional messages that you reviewed and the quantity of opioids in New York State, Long Island, or the Counties]?
>
> A. The promotional messages targeting doctors and other healthcare institutions led to increased prescribing of opioids, which led to a greater supply of opioids in the community.
>
> Q. And what did that lead to?
>
> A. That led to more people becoming addicted to opioids, more people overdosing on opioids, and more people dying from opioids.

In re Opioid Litig., No. 400000/2017, Trial Tr. 101:13–21 (N.Y. Sup. Ct. Suffolk Cnty. July 12, 2021), ECF No. 3859-16.

These courts had the benefit of the material outlined above that was not presented to this Court in Track One.[4] This material demonstrates that Dr. Lembke is "qualified as an expert by knowledge" and "experience" to opine on a topic to which she has dedicated a substantial part of her professional activity for much of the past ten years. Fed. R. Evid. 702. The Court should allow the adversary process to weigh Dr. Lembke's opinions on the effect of the opioid industry's promotion of opioids on doctors, their prescribing practices, and the consequences for the nation's opioid supply.

Alternatively, if the Court continues to agree with Defendants on this point, the Court should give Defendants no more than what they have asked for: reaffirmation of the Court's

[4] Faced with similar evidence and argument as that before the two state courts and now before this Court, the Track Two transferor court granted defendants' motion to exclude Dr. Lembke's "marketing causation opinions" without discussion or analysis. *City of Huntington v. AmeriSource Berge Drug Corp.*, No. 3:17-01362, Order (S.D.W. Va. Apr. 29, 2021), S.D.W. Va. ECF. No. 1299, *attached as* Ex. D. That ruling provides no persuasive authority. Because the ruling was issue without an opinion, it is unclear whether the transferor court simply followed this Court's Track One ruling, or if it did not, what the basis for its conclusion was.

Track One ruling. *See* Defs.' Br. Supp. 1, ECF No. 3802 (notice of service). As the Court made clear, that ruling "applie[d] narrowly" only to the causal inference itself and not to any of its premises, Opinion and Order 12 (Aug. 28, 2019), ECF No. 2549, *available at* 2019 WL 4054998, including the means of promotion, the false and misleading character of promotion, and prescribers' reliance on promotion as a general matter. *See id.* at 12–13. The ruling should be as narrowly applied here as it was in Track One.[5]

CONCLUSION

For the reasons explained above, Defendants' motion should be denied in full. Rule 403 and the opportunity for cross-examination address every concern Defendants' motion raises. The jury should be permitted to weigh for itself the opinions contained in Dr. Lembke's Track Three report.

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[5] The Court's prior ruling on "marketing causation" is not relevant to the admissibility of Dr. Lembke's opinions regarding investigation of red flags, use of the PDMP, or Defendants' failure to adequately employ such methods to prevent diversion.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 29th day of December 2021, I have electronically filed the foregoing with the Clerk of Court using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court's CM/ECF System.

/s/ Anthony D. Irpino
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